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9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K050625

Date of Summary Preparation: March 08, 2005

Manufacturer:
Sweden Diagnostics (Germany) GmbH
Munzinger Strasse 7
D-79111 Freiburg, Germany

510 (K) Contact Person:
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Device Name: Varelisa® ReCombi ANA Profile

Common Name:
Antinuclear antibody
immunological test system

Classification

Product Name	Product Code	Class	CFR
Varelisa® ReCombi ANA Profile	LJM	II	866.5100

Substantial Equivalence to

Varelisa® ReCombi ANA Profile (510(k) number: K993109)
Varelisa® Sm Abs (510(k) number: K042629)

Intended Use Statement of the New Device

Intended use/Indication for use

The Varelisa ReCombi ANA Profile EIA kit is designed for the qualitative determination of eight antinuclear antibodies in human serum or plasma to aid in the diagnosis of SLE (systemic lupus erythematosus), scleroderma (progressive systemic sclerosis and CREST syndrome), MCTD (mixed connective tissue disease), SS (Sjögren's syndrome) and polymyositis/dermatomyositis. The Varelisa ReCombi ANA Profile individually detects antibodies against dsDNA, U1 RNP (RNP 70 kDa,A,C), SmD, SS-A/Ro(52 kDa, 60 kDa), SS-B/La, Scl-70, CENP-B and Jo-1.

Special condition for use statement

The device is for prescription use only.

Special instrument requirements

A microplate reader capable of measuring OD at 450 nm and 620 nm is required.

General Description of the New Device

The new device is an enzyme-linked immunosorbent assay (ELISA) using microtiter plates as the solid phase. Plate wells each coated with 1 of 8 different ANA antigens are included to allow corresponding antibodies in the patient samples react with the immobilized antigens. The conjugate is rabbit anti-human IgG horseradish peroxidase (HRP), which uses 3, 3'5, 5' tetramethylbenzidine dihydrochloride (TMB) as substrate. The kit contains a calibrator and a negative control. The kit also contains sample diluent, wash buffer concentrate and stop solution.

Test Principle of the New Device

Varelisa ReCombi ANA Profile is an indirect noncompetitive enzyme immunoassay for the individual qualitative determination of dsDNA, U1 RNP (RNP 70 kDa, A, C), Sm (D), SS-A/Ro (52 kDA, 60 kDA), SS-B/La, Scl-70, CENP-B and Jo-1 antibodies in serum or plasma. The wells of a microplate are coated with human recombinant antigens, synthetic peptides or plasmid DNA. Antibodies specific for the nuclear antigens present in a patient sample bind to these nuclear antigens.
In a second step the enzyme labeled second antibody (conjugate) binds to the antigen-antibody complex which leads to the formation of an enzyme labeled conjugate-antibody-antigen complex. The enzyme labeled antigen-antibody complex converts the added substrate to form a colored solution.

The rate of color formation from the chromogen is a function of the amount of conjugate complexed with the bound antibody and thus is proportional to the initial concentration of the respective antibodies in the patient sample.

Device Comparison

Varelisa ReCombi ANA Profile (Art No 12996) vs (Art No 18496)

The new device is developed as successor of the predicate device Varelisa ReCombi ANA Profile (Art No 12996). Both assays are indirect noncompetitive

enzyme immunoassays for the qualitative determination of IgG antibodies against seven antinuclear proteins and dsDNA in serum and plasma. Both assays recommend the same sample dilutions and use identical reagents (including the conjugate). In accordance to the relevant scientific literature both assays state in the Intended Use, that the measuring of antinuclear antibodies provides aid in the diagnosis of SLE (systemic lupus erythematosus), scleroderma (progressive systemic sclerosis and CREST syndrome), MCTD (mixed connective tissue disease), SS (Sjögren's syndrome) and polymyositis/ dermatomyositis.

The difference between the assays is the use of a synthetic peptide derived from the human SmD protein instead of internally produced native Sm antigen (complex consisting of SmBB' and SmD) purified from calf thymus. Further information on the synthetic SmD peptide is given in the submission of the quantitative assay Varelisa Sm Abs (K042629). For additional information of the customer an "Included Information Sheet" will be performed (see Chapter 4.5). Minor differences pertain to different volumes of the reagents.

Varelisa Sm Abs (Art No 18296) vs ReCombi ANA Profile (Art No 18496)

The new device and the predicate device Varelisa Sm Abs, both are indirect noncompetitive enzyme immunoassays for the qualitative determination of IgG antibodies against SmD antigens. Both assays recommend the same sample dilutions and use identical reagents (including the conjugate). The solid phase strip used in the new devise is identical to the solid phase used in the predicate device. In accordance to the relevant scientific literature both assays state in the Intended Use, that the measuring of SmD antibodies in serum or plasma aids in the diagnosis of systemic lupus erythematosus (SLE).

Laboratory equivalence

The comparability of predicate devices and new device is supported by a data set including

- results obtained within a comparison study analyzing positive, equivocal and negative sera.
- results obtained for international reference sera.
- results obtained for samples from apparently healthy subjects (normal population).

In summary, all available data support that the new device is substantially equivalent to the predicate device and that the new device performs according to state-of-the-art expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 26 2005

Sweden Diagnostics (Germany) GmbH
c/o Sabine Klugbauer, Ph.D.
Specialist, Regulatory Affairs
Munzinger Strasse 7
D-79111 Freiburg

Re: k050625
Trade/Device Name: Valelisa® ReCombi ANA Profile
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear Antibodies Immunological Test System
Regulatory Class: Class II
Product Code: LJM
Dated: March 8, 2005
Received: March 11, 2005

Dear Dr. Klugbauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0131. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: **K050625**

Device Name: **Varelisa® ReCombi ANA Profile**

Indications For Use:

The Varelisa ReCombi ANA Profile EIA kit is designed for the qualitative determination of eight antinuclear antibodies in human serum or plasma to aid in the diagnosis of SLE (systemic lupus erythematosus), scleroderma (progressive systemic sclerosis and CREST syndrome), MCTD (mixed connective tissue disease), SS (Sjögren's syndrome) and polymyositis/dermatomyositis. The Varelisa ReCombi ANA Profile individually detects antibodies against dsDNA, U1 RNP (RNP 70 kDa,A,C), SmD, SS-A/Ro(52 kDa, 60 kDa), SS-B/La, Scl-70, CENP-B and Jo-1.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050625